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Croatia

Agricultural Biotechnology Annual

Update

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Report Highlights:
Croatia is a net food importer and government policy is geared towards raising agricultural productivity and, to a lesser extent, limiting imports. EU membership is a priority for the Croatian government, and new laws and agricultural policies mirror those of the EU. The Croatian public remains very skeptical about agricultural biotechnology. There has also been a general demonization of U.S. food products as "Frankenstein Foods." In Croatia, several pieces of legislation have been introduced to regulate the importation and cultivation of biotech crops and foods.

Section I. Executive Summary:

Croatia is a net food importer. The primary goal of agricultural policy is to increase productivity, and to a lesser extent, limiting imports. EU membership is a priority for the Croatian government, and new laws and agricultural policies mirror those of the EU.

The Croatian public remains very skeptical about agricultural biotechnology and consumers often consider U.S. food products to be "Frankenstein Foods."

In 2004, the government randomly tested samples of foodstuffs and seed taken from the market for biotech traces, which resulted in the withdrawal of some products due to improperly labeling of products containing biotech. The Croatian Government then penalized the importers.

Several pieces of legislation regulate the importation and cultivation of biotech crops and foods. The laws regulating biotechnology include the Food Act and the Law on Genetically Modified Organisms. Additional important legal documents on biotechnology include Government Ordinances on GMO Levels in Products Under Which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO (Governmental Gazette 92/2008, Governmental Gazette 36/2009, Governmental Gazette 33/2010, Governmental Gazette 88/2011, and Governmental Gazette 39/2012). These ordinances list the biotech events that can be contained in a product in trace amounts.

Section II. Plant Biotechnology Trade and Production:

a. Croatia does not commercially produce biotech crops or seeds.

b. Croatia is not developing any biotech crops.

c. In Croatia there are no approved biotech crops for food or feed, but there is a 0.9% threshold level for biotech events in food and feed that are on the official list (Section III) of permitted GMO events (the list is created from the list of biotech events previously tested and licensed in the EU and was published in Croatia as Ordinance in 2008 with amendments in 2009, 2010, 2011 and 2012). If the biotech event is on the list and is present in the product up to 0.9%, it does not need to be labeled for sale on the Croatian market. However, if the biotech content is above 0.9%, the product must be labeled as GM. The biotech threshold level drops to 0.0% for biotech products that are not on the list of permitted events. The same applies to feed. Officially Croatia does not import biotech crops/products because GM labeling is mandatory and currently there are no GM labeled products on the market.

d. Croatia is not a food aid recipient.

e. Croatia does not produce any biotech crops developed outside of the United States or any biotech crops in general.

Section III. Plant Biotechnology Policy:

a. Agricultural biotechnology regulatory framework:

The Food Act governs the possible importation, licensing, and labeling of any foods/feed containing biotech ingredients. Parliament approved the latest Food Act on April 25, 2007 and published in

Government Gazette number 46 on May 7, 2007. This law outlines many regulations that would enable biotech products to enter the market and be labeled. Publication of many of those regulations was on hold until the approach of Croatian EU accession when many regulations had to be published. The four government ordinances regulate the labeling threshold for biotech content *("GMO Levels in Products Under Which Products Placed on the Market Do Not Have to be Labeled as Products Containing GMO") passed on July 31, 2008, (Governmental Gazette 92/2008); March 18, 2009 (Governmental Gazette 36/2009); March 11, 2010 (Governmental Gazette 33/2010*); *April 2, 2011 (Governmental Gazette 88/2011); and March 2012 (Governmental Gazette 39/2012)* (see section IIIbi for additional details). Penalties for companies violating the "novel food" provisions of the Food Law concerning placing novel foods on the market and/or labeling them range from HRK 100,000 to HRK 500,000($ 17,034 – $ 85,169), with responsible individuals fined from HRK 5,000 to HRK 10,000 ($ 852 – $ 1,703).

The Law on Genetically Modified Organisms (Law on GMOs) is an overarching law for biotechnology. The Law on Genetically Modified Organisms (Governmental Gazette 70/2005, 137/2009) together with the Food Act and subsequent regulations regulate the importation, transshipment, production, usage, and sale of products of agricultural biotechnology (all food, feed, and seed). This Law established a testing and licensing regime that is very restrictive. The highest penalties for breaching the provisions of this Law range from HRK 500,000 to HRK 1,000,000 ($ 85,169 – $ 170,338) for the responsible company and from HRK 20,000 to HRK 70,000 ($ 3,407 - $ 11,924) for the responsible employee in the company.

i. Responsible Ministries and Their Roles:

Ministry of Science (MOS), Education and Sport: According to the Law on GMOs, the MOS is responsible for the limited and contained use of GMOs.

Ministry of Health (MOH): According to the Food Act, the MOH is responsible for all the issues regarding food, foodstuff, and feed containing biotechnology content and inspections. Additionally, the Law on GMOs proscribes that MOH is responsible for the usage and inspection of the GMO products in cosmetics, pharmaceutical products, and products for human health protection. According to the Law on GMOs, the MOH is the umbrella ministry and coordinating body for all biotechnology issues.

Service for Biodiversity in the Ministry of Environment and Nature Protection (MENP) that in 2012 replaced Environment Protection Directorate in the Ministry of Culture (MOC): According to the Law on GMOs the MOC is responsible for the intentional introduction of GMOs into the environment.

Ministry of Agriculture(MOA): According to the Food Act, the Ministry of Agriculture is the central body of the Government responsible for food/feed safety, quality, and hygiene. This Ministry is also a contact point for the EU for related issues. The Ministry of Agriculture and the Ministry of Health have joint responsibility concerning all issues regarding food, foodstuff, and feed containing plant or animal biotechnology content and their inspections. According to the Law on GMOs, the MOA has responsibility for inspections of biotech feed; biotech reproduction material in agriculture and veterinary medicine; and drugs in veterinary medicine and pesticides. Furthermore, the MOA is responsible for giving its consent for the intentional release of biotech products into the environment.

State Inspectorate: According to the Law on GMOs, the State Inspectorate has responsibility for inspecting GMO labeling.

ii. Role and Membership of Biosafety Committee (if any):

The Law on GMOs required the establishment of a Council for GMOs with the specific task of assisting governmental bodies to apply the Law. The Council has 17 members appointed by the Government of Croatia based on nominations from the pertinent Ministries. Council membership lasts for four years. The Council's work is independent and public. According to the Law, the Council's tasks include: tracking gene technology development and usage, tracking scientific breakthroughs and giving opinion and incentives for usage of gene technology and GMOs, giving opinions on social, ethical, technical, scientific, and other conditions of GMO use, advising responsible institutions on GMO and gene technology issues, informing the public on GMO and gene technology development, and presenting viewpoints and opinions.

The Law on GMOs also calls for establishing a Board for Limited Usage of GMOs with 11 members composed of scientists from the fields of microbiology, genetics, medicine, biochemistry, molecular biology, pharmacy, biotechnology, agriculture, forestry, veterinary medicine, nature and environmental protection, and occupational protection. In addition, the Law on GMOs requires the establishment of a board for the introduction of biotech products into the environment that consists of nine scientists from the fields of: genetics, ecology, nature protection, environmental protection, agriculture, forestry, veterinary medicine, biochemistry, molecular biology, microbiology, and medicine. The tasks of these boards include: giving opinions on biotech usage in terms of legal procedures as outlined by the Law on GMOs; giving opinions and proposals for preparing other legislation on GMO usage; and giving opinions and proposals to responsible ministries on biotech usage issues and other expert work as outlined by the GMO Law and related regulations. According to the law, these two boards should report to the GMO Council once a year.

The old and new Food Act/s called for the establishment of the Croatian Food Agency, which began its work in 2004. The Agency's work consists of providing scientific and technical support to legislators as well as providing scientific advice in all areas that have direct and indirect influence on food and feed safety. Additionally, the Food Agency is required to work on many other issues concerned with feed, food, and nutrition and provides scientific opinions to the Ministry of Health and the Ministry of Agriculture regarding the placement of GMO food and/or feed on the market.

iii. Assessment of political factors that may influence regulatory decisions related to agricultural biotechnology:

Although EU membership is a priority for the Croatian government and the country's new laws and agricultural policies mirror those of the EU, biotech opponents in Croatia have been emboldened by the perceived success of Austria and Slovenia in standing up to the European Commission on biotech approvals. Thus, complying with EU regulations has little meaning as long as Croatia positions itself within a regional group of "healthy," GMO-free countries.

Currently, Croatia clearly sees its future as a "niche market for healthy food" (NOTE: In Croatia, the word "healthy" encompasses everything from conventional and organic to non-biotech products), and

biotech seed imports are not necessary for Croatia given a lack of agricultural demand for biotech products to combat drought, pests, or soil problems. Government officials acknowledge the legal obligation to open their agricultural market to foreign imports and openly acknowledge that Croatia is positioning itself as a GMO-free, "healthy" tourist destination. The Croatian public is generally very opposed to biotech products.

iv. Distinctions between the regulatory treatment of approval for food, feed, processing, and environmental release are the following:

There are similar long and complicated procedures to approve food and feed products, but the approval process for environmental release is different. At the end of the regulatory procedure for food and feed, biotech products must gain special permission to market the product. Some agricultural seed varieties (biotech and conventional); however, must first go through a variety registration process. After the Croatian Seed and Seedlings Institute registers the variety, it is placed on the list of seed varieties that can be marketed in Croatia. Biotech seeds, in additional to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GMOs.

b. Biotechnology crops approved for:

i. Food, processing and feed:

Croatia has not approved any biotech crops for food or feed use in Croatia, but there is a 0.9% threshold level for some biotech events in food and feed. Under a special ordinance from 2008 and its amendments from 2009, 2010, 2011 and 2012 the threshold for biotech content in food depends upon whether or not the biotech event is on the Ordinance's list of permitted GMO events (the list is created from the list of biotech events previously tested and licensed in the EU). If the biotech event is on the Ordinance's list, it does not need to be labeled for sale on the Croatian market--provided separate tests within Croatia confirm that the product contains up to 0.9% biotech content (for products that consist of more than one ingredient, the 0.9% threshold is permitted per product's ingredient). However, if the biotech content is above 0.9%, the product must be labeled. The biotech threshold level drops to 0.0% for biotech products that are not on the Ordinance's list. The same applies to feed.

List of GMOs allowed up to the 0.9% threshold level:

Num.	Code	Plant	Producer	Modification	Possible Usage
1.	Carnation Moonlite (Dianthus caryophyllus L. line 123.2.38)	carnation	Florigene Ltd	flower color	import and processing
2.	Carnation Mooshadow 1	carnation	Florigene Ltd	flower color	cultivating
3.	Carnation	carnation	Florigene Ltd	long life	

	Moonshadow 2				
4.	Carnation Moondust	carnation	Florigene Ltd	flower color	import and processing
5.	1507	corn	Pioneer/Dow AgroScience	insect resistance **Lepidoptera** *(Ostrinia nubilalis)* and herbicide tolerance	food and feed
6.	59122	corn	Pioneer Hi-Bred/Mycogen seeds	insect resistance and herbicide tolerance	food, food ingredient and feed
7.	1507 X NK603	corn	Pioneer Hi-Bred/Mycogen seeds	insect resistance and herbicide tolerance	
8.	MON863	corn	Monsanto	insect resistance	food, feed and processing
9.	GA21	corn	Syngenta	herbicide tolerance	
10.	MON863X MON810	corn	Monsanto	insect resistance	food, feed and cultivating
11.	NK603	corn	Monsanto	herbicide tolerance	* food, food ingredients and feed * products different than food and feed with exception of cultivation
12.	Bt11	corn	Syngenta	insect resistance and herbicide tolerance	
13.	MON810	corn	Monsanto	herbicide tolerance	
14.	T25	corn	Monsanto	herbicide tolerance	
15.	MON863 X NK603	corn	Monsanto	insect resistance and herbicide tolerance	
16.	NK603 X MON810	corn	Monsanto	insect resistance and herbicide tolerance	
17.	MON1445	cotton	Monsanto	herbicide tolerance	
18.	MON531	cotton	Monsanto	insect resistance	

19.	MON15985	cotton	Monsanto	herbicide tolerance	
20.	MON15985 X MON1445	cotton	Monsanto	insect resistance and herbicide tolerance	
21.	MON531 X MON1445	cotton	Monsanto	insect resistance and herbicide tolerance	
22.	MON40-3-2	soybean	Monsanto	herbicide tolerance	* food, feed and food and feed ingredients * products different than food and feed with exception of cultivation
23.	MS8 X RF3	canola	Bayer CropScience	sterility, herbicide resistance	food, feed, import and processing
24.	GT73	canola	Monsanto	herbicide resistance	
25.	T45	canola	Bayer CropScience	herbicide resistance	food and feed
26.	H7-1	sugar beet	KWS Saat AG/Monsanto	herbicide resistance	food, food ingredients and feed
27.	A2704-12	soybean	Bayer CropScience	herbicide resistance	* food, food ingredients and feed * products different than food
28.	LL Cotton 25	cotton	Bayer CropScience	herbicide resistance	
29.	MON-89788-1	soybean	Monsanto Europe S.A	herbicide resistance	
30.	T45	canola	Bayer	herbicide tolerance	

			CropScience		and feed with exception of cultivation
31.	MON 88017	corn	Monsanto Europe SA	insect resistance and herbicide tolerance	
32.	59122xNK603	corn	Pioneer Overseas Corporation	insect resistance and herbicide tolerance	
33.	MON 89034	corn	Monsanto Europe SA	insect resistance	
34.	MIR604	corn	Syngenta Seeds S.A.S.	insect resistance (*Diabrotica* spp.)	
35.	EH92-527-1	starch potato*(Solanum tuberosum L.)*	BASF	Changed starch type (higher content of amylopectin when compared with amylosee) nptII gen used as selection marker	* food, feed and food and feed ingredients * for cultivation
36.	MON 863xMON810x NK603	corn	Monsanto	insect resistance **Coleoptera** (*Diabrotica spp.*), **Lepidoptera**(*Ostrinia nubilalis, Sesammia spp.*) and herbicide tolerance nptII gen used as selection marker	* food, feed and food ingredients * products different than food and feed with exception of cultivation
37	MON863xMON810	corn	Monsanto	insect resistance **Coleoptera** (*Diabrotica spp.*), **Lepidoptera**(*Ostrinia nubilalis, Sesammia spp.*) nptII gen used as selection marker	* food, feed and food ingredients * products different than food and feed with exception of cultivatio

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38.	MON863xNK603	corn	Monsanto	insect resistance **Coleoptera** (*Diabrotica spp.*), and herbicide tolerance nptII gen used as selection marker	* food, feed and food ingredients * products different than food and feed with exception of cultivation
39.	MON89034xNK603	corn	Monsanto	insect resistance **Lepidoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
40.	Bt11xGA21	corn	Syngenta	insect resistance **Lepidoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
41.	59122x1507xNK603	corn	Pioneer	insect resistance **Lepidoptera, Coleoptera,** and	* food, feed and food

				herbicide tolerance	ingredients * products different than food and feed with exception of cultivation
42.	MON88017xMON 810	corn	Monsanto	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
43.	1507x59122	corn	Dow AgroSciences and Pioneer Overseas Corporation	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
44.	GHB614	cotton	Bayer Crop Science	Insect resistance, and herbicide tolerance	* food, feed and food ingredients * products different

					than food and feed with exception of cultivation
45.	MON 89034 x MON 88017	corn	Monsanto	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
46.	Bt11x MIR 604 xGA21	corn	Syngenta Seeds	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
47.	Bt11xMIR 604	corn	Syngenta Seeds	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception

					of cultivation
48.	281-24-236x3006-210-23	corn	Syngenta Seeds	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation
49.		cotton	Dow AgroSciences Europa	insect resistance **Lepidoptera, Coleoptera,** and herbicide tolerance	* food, feed and food ingredients * products different than food and feed with exception of cultivation

ii. Environment:

Croatia has not approved any biotech seed variety for planting. In addition, there are no seed varieties in the process of approval. Thus, currently, there is a de facto ban on biotech seed plantings in Croatia with a biotech seed threshold level in regular varieties of 0.0%.

c. Situation for within-country biotech crop field-tests:

According to the Law on GMOs and consequent Regulations, field tests of biotech crops are allowed after all the conditions prescribed by the Law and Regulations are satisfied. However, such tests are not conducted in Croatia.

d. Treatment of stacked events:

To date, Croatian legislation does not specifically deal with or specifically outline the treatment of stacked events. Future regulations may address this issue.

e. Additional product registration required, above and beyond approval, prior to use:

Biotech food and feed products require special permission as GMO products to be placed on the market and permission as GMO food and/or feed products to be placed on the market. Additionally, some agricultural seed varieties (regular and biotech) must go through a variety registration process before they are placed on the list of seeds that can be marketed in Croatia. Biotech seeds, in addition to variety registration, require special permission to be placed on the market, including permission for the intentional environmental release of GMOs.

f. Legal framework for coexistence between biotech and non-biotech crops:

The Law on GMOs forbids planting of registered biotech crops in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, in protected areas (i.e. as defined as protection impact zones with previously enlisted zones), and in areas that were defined by local government as GMO-free zones.

In addition, biotech crop plantings for reproduction are allowed only in the areas that are designated by the Ministry of Agriculture and the Ministry of Environment and Nature Protection and approved by the Croatian Government in a special ordinance.

g. Labeling of packaged foods or feeds:

According to the Food Act, food and feed containing agricultural biotechnology ingredients must have special, additional information on the label that informs consumers of all of its characteristics.

h. Biosafety Protocol:

Croatia signed and ratified the Cartagena Biosafety Protocol. Officially, there is no trade in biotech products, especially not in seeds. However, it is currently difficult to tell whether the Biosafety Protocol is being applied and working in practice.

i. Croatia is a member of the International Plant Protection Convention (IPPC), Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE), but Croatia does not appear to take an active position regarding plant biotechnology in these organizations.

j. The Croatian legislative framework for biotechnology is very strict and Croatian consumers are very negative towards modern, biotech foods.

k. Beyond current legislation, there is no additional pending, plant-biotechnology legislation with potential to affect U.S. exports. A potential future exception could be legislation regarding bioengineered animals.

l. Biotech crops are not planted commercially in Croatia. Croatia has intellectual property rights legislation in place and is a member of The International Union for the Protection of New Varieties of Plants (UPOV).

Section IV. Plant Biotechnology Marketing Issues:
a. Market acceptance issues:

The average Croatian consumer views food derived from biotech crops negatively. Farmers are afraid to grow biotech crops. There is a feeling that biotechnology is something unnatural and that food should be natural. These negative opinions are based largely on emotions.

b. Country-Specific Studies on Acceptance of Biotechnology:

A Croatian market research agency carried out a study in 2009 on "consumers' recognition of healthy food" that among other things researched the opinions and knowledge of Croatian consumers on GMOs. In this study, 51% of respondents said that they would not eat GMO food products under any circumstances and 29% of respondents thought that they did not know enough about GM foodstuffs. The study showed that 90% of respondents thought that GM foodstuffs should be clearly labeled on the store shelves.

The same agency did a study in 2005and 2008 on public opinion on GMOs. In this study, 67% (2005) and 58% (2008) of respondents said that they would not eat GM food products under any circumstances and only 16% (2005) and 26% (2008) of respondents thought that they didn't know enough about GM foodstuffs.

Section V. Plant Biotechnology Capacity Building and Outreach:
a. List of the U.S. Government / USDA funded capacity-building / outreach activities that have been carried out in Croatia over the past two years:

2012: Sponsorship of a speaker for a feed conference (KRMIVA): The topic of the conferences was Animal Feed, and FAS Zagreb provided a speaker on the following topic - "Bt Corn in Italy: a missed opportunity for farmers and feeders".

2011: Sponsorship of a speaker for a feed conference (KRMIVA): The topic of the conferences was Animal Feed, and FAS Zagreb provided a speaker on the following topic - "Asynchronous Authorization and the Low-level Presence of Unauthorized GMOs and GM-derived Materials in Imports of Feed Commodity Crops from outside the European Union".

2009: Sponsorship for of a speaker for a feed conference (KRMIVA): The topic of the conference was Biotechnology in Feed for which U.S. Grains Council (funding) and USDA (logistics) sponsored a speaker.

Section VI. Animal Biotechnology:
I. Development and Use:

a. Genetic engineering and cloning are not practiced in Croatia for the development of agricultural animals.

b. There are no genetically engineered animals or products derived from the animals intended for or currently in commercial production in Croatia.

II. Regulation:

a. Croatia does not have in place any legislation specifically related to the development, commercial use and/or import of these animals or products. However, last amendment to the Law on GMOs (Governmental Gazette 137/2009) mentions briefly that it is forbidden to plant registered biotech crops *or breed registered biotech animals* in nature-protected areas, ecological areas, areas for organic agricultural production or eco-tourism, in protected areas (i.e. as defined as protection impact zones with previously enlisted zones) and in areas that were by local government defined as GMO-free zones. Additionally the Law on GMOs mentions that The Ministry of Agriculture and the Ministry of Health have joint responsibility concerning all issues regarding food, foodstuff, and feed containing plant *or animal biotechnology* content and their inspections.

b. Currently, the FAS office in Croatia is not aware of any discussions of related regulatory or research policies on these technologies.

c. Government entities that would likely regulate these technologies, regarding both food and environmental safety issues related to research on or commercial use of these animals, include: Ministry of Agriculture; Ministry of Health; Ministry of Environment and Nature Protection; Ministry of Science, Education and Sport; Croatian Food Agency, and Council for GMOs.

d. Labeling and/or traceability of these animals or products is expected to be an issue in Croatia. There are indications that the Croatian Government might require mandatory labeling of products derived from GE or cloned animals.

III. Stakeholder/Public Opinions:

a. There are active organizations that lobby against the genetic engineering or cloning of agricultural animals. In addition, the Croatian press is expected to actively oppose this technology.

b. In Croatia, it can be expected that the market would reject these products.

IV. International Organizations:

a. We are not aware that Croatia actively participates in discussions in international organizations related to the genetic engineering of agricultural animals.

V. Outreach, Needs, and Strategies:

a. Croatia is strongly opposed to bioengineering in plants and efforts to promote animal biotechnology

are unlikely to succeed.

Section VII. Author Defined:
Average exchange rate for May 2012 $1:Kn 5,870676